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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,172	03/19/2004	Leonard C. Jannusch	8195.35US01	7390

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EXAMINER

MAHYERA, TRISTAN J

ART UNIT	PAPER NUMBER
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4173

MAIL DATE	DELIVERY MODE
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10/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/805,172

Applicant(s)

JANNUSCH ET AL.

Examiner

Tristan J. Mahyera

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 45-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 and 45-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/4/2007, 11/14/2005, 9/23/2005, 8/8/2005, 7/2/2004.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-33 and 45-49 in the reply filed on 09/04/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

The amendment filed 07/02/2004 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: 30 milligrams.

Applicant is required to cancel the new matter in the reply to this Office Action. If applicant believes support does exist for 30 milligrams, applicant is encouraged to refer examiner to a page and line number.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 3 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 3 and 28 require a percent fatty alcohol content of the film capable of keeping the temperature range required to change the film from a solid to a liquid within 20 degrees Celsius or less. However, the specification does not clearly, concisely or exactly describe teaching how to determine the percent fatty alcohol necessary to achieve the desired melting range. Thus, a person of skill in the art would be unable to clearly envisage the claimed film composition. If applicants believe sufficient description is provided, applicants are encouraged to point to a specific page and line.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-33 and 45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over ZERBE et al. (US 7,132,113) in view of CHEN et al. (US 2003/0118653) and in view of ENGLESON et al. (US 7,153,531).

Claims 45-49 are product by process claims. It is deemed that the process does not result in a structurally different product, thus the process steps have been given little weight.

ZERBE discloses a rapidly disintegrating flavored film wherein hydroxypropyl cellulose was used in combination with starches, surfactants and flavors. See column 2 lines 10-15 and claim 1. The edible film can be used for breath freshening agents or to impart flavor to food, however, the use of film for administration of therapeutic agents or medicaments are well known in the art. See column 1 lines 16-33 and column 2 lines 41-52. The films are moisture free and contain about 20-70% hydroxypropyl cellulose,

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from about 5-70% modified starch and up to about 60% of flavorants. See column 3 lines 37-41. The films may contain other ingredients such as surfactants, other film-forming polymers and wetting agents. In certain applications ZERBE teaches that it would be desirable to increase the wettability of the film by adding surfactants. See column 3 lines 41-46. Numerous flavor oils can be added to the film, for example, peppermint, citrus or fruit flavors. See column 4 lines 57-60. The film will preferably disintegrate in less than 30 seconds. See column 5 lines 5-8. The thickness of the film while preferably 10 micrometers to about 200 micrometers can be thicker or thinner depending on the application. See column 5 lines 25-28.

ZERBE does not disclose the use of fatty alcohols, but suggests or motivates the use of surfactants or other film forming polymers. See column 3 lines 41-46. ZEBRE does not disclose dextrose or other carbohydrates, however, the addition of bulking agents e.g. dextrose is well known in the art and within the ordinary skill of a person practicing the pharmaceutical or food composition arts. See ENGLESON claim 4.

CHEN discloses a quick dissolving oral mucosal drug delivery film having a mucosal surface-coat forming layer and moisture barrier layers wherein a active agent is administered. See paragraph [0002]. The moisture barrier acts a control for the release of the active agent e.g. medicament, wherein the melting point of the layer is in excess of 45 degrees Celsius. See paragraph [0075]. The barrier layer can be fatty alcohols, specifically, cetyl or stearyl alcohol. See paragraph [0075]. The fatty alcohols can be used from 10 to 90% by weight. See paragraph [0078]. CHEN further discloses

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sweeteners, flavorants and essential oils from 1 to 40% by weight see paragraphs [0025], [0076] and [0078].

Claims 1, 16-18, 20-23, 25, 26 and 31-33 define specific ranges of wt%, perimeter area or thickness that can be found through routine optimization. See MPEP 2144.05 "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert.

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denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997)."

Therefore, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the combination of hydroxypropyl cellulose and a fatty alcohol with bulking agents, flavorants or medicaments to form an edible film, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tristan J. Mahyera whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TJM/


CECILIA TSANG
SUPERVISORY PATENT EXAMINER